

FDA Preliminary Public Health Notification*: Recall of Boston Scientific ENTERYX® Procedure Kits and ENTERYX® Injector Single Packs for Treatment of Gastroesophageal Reflux Disease (GERD)

October 14, 2005

Dear Health care practitioner:

This is to let you know about serious adverse events, including death, occurring in patients treated with Boston Scientific's ENTERYX® for gastroesophageal reflux disease (GERD), and to provide recommendations on avoiding future occurrences.

On September 23, 2005, Boston Scientific Corporation issued a recall of ALL ENTERYX® Procedure Kits and ENTERYX® Injector Single Packs from commercial distribution. ***Physicians should stop injecting ENTERYX® immediately and follow the manufacturer's procedures for returning unused product.***

Nature of the Problem

ENTERYX® is a liquid chemical polymer which is intended to be injected into the lower esophageal sphincter. The device polymerizes into a spongy material shortly after injection and once injected cannot be removed.

The serious adverse events involve unrecognized transmural injections of ENTERYX® into structures surrounding the esophagus. Transmural injections can potentially result in death or serious injury. Signs and symptoms of transmural injection can potentially include: chest pain, flu-like symptoms, pneumonia, atelectasis, reactive pneumonitis, mediastinitis, pneumo-mediastinum, reactive pleuritis, pleural effusion, pericardial effusion, syncopal episodes, and flank pain. Some cases of transmural injection were not recognized at the time of the procedure or during immediate follow-up; these occurred even though fluoroscopy was used throughout the procedure. Three weeks was the longest period that we know of in which a transmural injection went unrecognized by a physician.

At this time, it is not possible to provide accurate estimates of the number of adverse events associated with transmural injection of ENTERYX®, or to describe all of the possible outcomes. Reports received thus far suggest ENTERYX® has been injected into various sites outside the esophagus including the mediastinum, pleural space and the aorta. When injected into the aorta, ENTERYX® may migrate to and occlude blood vessels which supply other organs including the kidneys. One reported death was due to injection of the ENTERYX® into the wall of the aorta, which resulted in an aorto-enteric fistula. Another patient experienced a partial reduction in renal function due to partial

embolization. It is not known at this point whether ENTERYX[®] injected outside the esophagus can be removed.

FDA is aware that not all injuries are caused by user technique or transmural injection. Recent literature cites 2 cases in which serious mediastinal events suggestive of possible inflammatory reactions occurred even though proper procedure was followed. Other adverse events not associated with transmural injection have also been reported to the FDA, some of them presenting 4 to 7 weeks after ENTERYX[®] injection. They include dysphagia from esophageal stenosis or stricture that required dilation procedures, and weight loss. These later-onset events appear to be different from the immediate onset, short-lived events observed during the approval trial for ENTERYX[®].

Recommendations

Physicians are advised to immediately stop using ENTERYX[®].

If transmural injection of ENTERYX[®] has occurred or is suspected at the time of implantation, the patient should be monitored carefully for at least 30 days.

For ***all*** patients who have received ENTERYX[®], we recommend that you:

1. advise your patients to seek medical evaluation immediately if they experience the onset of symptoms which may indicate transmural injection. These include chest or epigastric pain, flu-like or respiratory symptoms (fever, cough, shortness of breath), syncope or flank pain. You may wish to provide them with a copy of FDA's "Advice for Patients with ENTERYX[®] for Gastroesophageal Reflux Disease," available at <http://www.fda.gov/cdrh/medicaldevicesafety/atp/101405-enteryx.html>.
2. perform tests, as clinically indicated, including chest x-rays, barium swallows, and/or chest/abdominal CT scans to confirm or rule out transmural injection.
3. advise patients to:
 - continue with their regularly-scheduled follow-up appointments; and
 - go *immediately* to an emergency room if they experience chest pain or syncope.

Since physicians should no longer be implanting ENTERYX[®], the FDA is not making recommendations about techniques in using the product.

Reporting Adverse Events to FDA

FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices. If you suspect that a reportable adverse event was related to the use of ENTERYX[®], you should follow the reporting procedure established by your facility. Prompt reporting of adverse events can improve FDA's understanding of and ability to communicate the risks associated with devices and assist in the identification of potential future problems.

We also encourage you to report adverse events related to ENTERYX[®] that do not meet the requirements for mandatory reporting. You can report these directly to the device manufacturer. You can also report to MedWatch, the FDA's voluntary reporting program. You may submit reports to MedWatch by phone at 1-800-FDA-1088; by FAX at 1-800-FDA-0178; by mail to MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-9787; or online at <http://www.fda.gov/medwatch/report.htm>. Consumers can also report directly to MedWatch.

Getting More Information

For more information about the recall, contact Boston Scientific Corporation at 1-800-862-1284. If you have questions for a physician about the recall, contact Boston Scientific's Associate Medical Director, Gaby Baramki, M.D., at 508-683-4212.

If you have questions about this Notification, please contact Julia Marders, Office of Surveillance and Biometrics (HFZ-510), 1350 Piccard Drive, Rockville, Maryland, 20850, Fax at 301-594-2968, or by e-mail at phann@cdRH.fda.gov. You may also leave a voice mail message at 301-594-0650 and we will return your call as soon as possible.

FDA medical device Public Health Notifications are available on the Internet at <http://www.fda.gov/cdrh/safety.html>. You can also be notified through email on the day the safety notification is released by subscribing to our list server. To subscribe, visit: <http://list.nih.gov/archives/dev-alert.html>.

Sincerely yours,



Daniel G. Schultz, MD
Director
Center for Devices and Radiological Health
Food and Drug Administration

* CDRH Preliminary Public Health Notifications are intended to quickly share device-related safety information with healthcare providers when the available information and our understanding of an issue are still evolving. We will revise them as new information merits and so encourage you to check this site for updates.

